PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the Supporting Statement and any additional documentation to: **Office of Informationand Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW Washington, DC 20503**.

1. Agency/Subagency originating request
EPA, Office of Prevention, Pesticides & Toxic Substances

2. OMB control number b. ☐ None
a. **2 0 7 0 - 0 0 3 9** __ __ __ __

3. Type of information collection *(check one)*
a. ☐ New collection
b. ■ Revision of a currently approved collection
c. ☐ Extension of a currently approved collection
d. ☐ Reinstatement, **without change**, of a previously approved collection for which approval has expired
e. ☐ Reinstatement, **with change**, of a previously approved collection for which approval has expired
f. ☐ Existing collection in use without an OMB control number

For b-f, note item A2 of Supporting Statement Instructions

4. Type of review requested *(check one)*
a. ■ Regular
b. ☐ Emergency - Approval requested by: ___/___/___
c. ☐ Delegated

5. Small entities
Will this information collection have a significant economic impact on a substantial number of small entities? ☐ Yes ■ No

6. Requested expiration date
a. ■ Three years from approval date b. ☐ Other Specify: __/__/___

7. Title **Submission of Unreasonable Adverse Effects Information Under FIFRA Section 6(a)(2**

8. Agency form number(s) *(If applicable)* EPA ICR #1204.05

9. Keywords Pesticides; Pest; Unreasonable Adverse Effects; Information; FIFRA; Registration; Producer; Reporting

10. Abstract **Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires pesticide registrants to submit information to the Agency that they acquire which may be relevant to the balancing of the risks and benefits of a pesticide product.**

11. Affected public *(Mark primary with "P" and all others that apply with "X")*
a. __ Individuals or households d. __ Farms
b. X Business or other for-profit e. __ Federal Government
c. __ Not-for-profit institutions f. __ State, Local or Tribal Government

12. Obligation to respond *(Mark primary with "P" and all others that apply with "X")*
a. ☐ Voluntary
b. ☐ Required to obtain or retain benefits
c. ■ Mandatory

13. Annual reporting and recordkeeping hour burden
a. Number of respondents 2,100
b. Total annual responses 45,540
1. Percentage of these responses collected electronically 5 %
c. Total hours requested 120,762
d. Current OMB inventory 10,380
e. Difference 110,382
f. Explanation of difference
1. Program Change 55,191
2. Adjustment 55,191

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*
a. Total annualized capital/startup costs
b. Total annual costs (O&M)
c. Total annualized cost requested
d. Current OMB inventory
e. Difference
f. Explanation of difference
1. Program change
2. Adjustment

15. Purpose of information collection *(Mark Primary With "P" and all others that apply with "X")*
a. __Application for benefits e. __Program planning or management
b. __Program evaluation f. __Research
c. __General purpose statistics g. X Regulatory or compliance
d. __Audit

16. Frequency of recordkeeping or reporting *(check all that apply)*
a. ☐ Recordkeeping b. ☐ Third party disclosure
c. ■ Reporting
1. ■ On occasion 2. ☐ Weekly 3. ☐ Monthly
4. ☐ Quarterly 5. ☐ Semi-annually 6. ☐ Annually
7. ☐ Biannually 8. ☐ Other (describe)

17. Statistical methods
Does this information collection employ statistical methods?
☐ Yes ■ No

18. Agency contact *(person who can best answer questions regarding the content of this submission)*
Name: **Angela F. Hofmann, Director, Regulatory Coordination Staff**
Phone: 202-260-2922

OMB 83-I **10/95**

Fax-on-Demand
Telephone: (202) 401-0527
Item: 6051

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal agency, 1 certify that the collection of information encompassed by this request complies with 5 CFR 1320.9.

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It uses plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention periods for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):
- (i) Why the information is being collected;
- (ii) Use of information;
- (iii) Burden estimate;
- (iv) Nature of response (voluntary, required for a benefit, or mandatory);
- (v) Nature and extent of confidentiality; and
- (vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of the instructions);

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Program Official **Angela F. Hofmann, Director** **Regulatory Coordination Staff (OPPTS)**	Date
Signature of Senior Official or designee **Joseph Retzer, Director** **Regulatory Information Division** **Office of Regulatory Management and Evaluation (OPPE)**	Date

Certification Requirement for Paperwork Reduction Act Submissions

5 CFR 1320.9 reads "As part of the agency submission to OMB of a proposed collection of information, the agency (through the head of the agency, the Senior Official or their designee) shall certify (and provide a record supporting such certification) that the proposed collection of information --

"(a) is necessary for the proper performance of the functions of the agency, including that the information to be collected will have practical utility;

"(b) is not unnecessarily duplicative of information otherwise reasonably accessible to the agency;

"(c) reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency, including with respect to small entities, as defined in the Regulatory Flexibility Act 5 U.S.C § 601(6)), the use of such techniques as:

> "(1) establishing differing compliance or reporting requirements or timetables that take into account the resources available to those who are to respond;
> "(2) the clarification, consolidation, or simplification of compliance and reporting requirements; or collection of information , or any part thereof;
> "(3) an exemption from coverage of the collection of information, or any part thereof;

"(d) is written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond;

"(e) is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who are to respond;

"(f) indicates for each recordkeeping requirement the length of time persons are required to maintain the records specified;

"(g) informs potential respondents of the information called for under § 1320.8(b)(3); [see below]

"(h) has been developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected, including the processing of the information in a manner which shall enhance, where appropriate, the utility of the information to agencies and the public;

"(i) uses effective and efficient statistical survey methodology appropriate to the purpose for which the information is to be collected; and

"(j) to the maximum extent practicable, uses appropriate information technology to reduce burden and improve data quality, agency efficiency and responsiveness to the public."

NOTE: 5 CFR 1320.8(b)(3) requires that each collection of information:

"(3) informs and provides reasonable notice to the potential persons to whom the collection of information is addressed of:

> "(i) the reasons the information is planned to be and/or has been used to further the proper performance of the functions of the agency;
> "(ii) the way such information is planned to be and/or has been used to further the proper performance of the functions of the agency;
> "(iii) an estimate, to the extent practicable, of the average burden of the collection (together with a request that the public direct to the agency any comments concerning the accuracy of this burden estimate and any suggestions for reducing this burden);
> "(iv) whether responses to the collection of information are voluntary, required to obtain or retain a benefit (citing authority), or mandatory (citing authority);
> "(v) the nature and extent of confidentiality to be provided, if any (citing authority); and
> "(vi) the fact that any agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Supporting Statement

1. Identification of the Information Collection

a) Title: **Submission of Unreasonable Adverse Effects Information Under FIFRA Section 6(a)(2)**

Numbers: **OMB #2070-0039; EPA ICR No. 1204.05**

b) Short Characterization

This information collection stems from a non-discretionary statutory requirement. Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requires pesticide registrants to submit information to the Agency that they acquire which may be relevant to the balancing of the risks and benefits of a pesticide product. In CSMA and NACA v. EPA 484 F. Supp. 513 (1980), the District Court of the District of Columbia agreed with EPA that FIFRA Section 6(a)(2) covers all information relevant to EPA's determination of whether a pesticide may cause unreasonable adverse effects. The Court agreed that submissible information includes the same type of information as that provided by a registrant as part of an application for registration. The Court specifically rejected the argument that the responsibility for determining what constitutes an unreasonable adverse effect shifts to industry once EPA has granted a registration.

As such, the statute requires the registrant to submit any factual information that it acquires regarding adverse effects associated with its pesticidal products, and it is up to the Agency to determine whether or not that factual information constitutes an *unreasonable* adverse effect. In order to limit the amount of less meaningful information that might be submitted to the Agency, the EPA has limited the scope of factual information that the registrant must submit. The draft final rule would serve to limit this scope even further by providing a more detailed description of the reporting obligations of registrants under FIFRA §6(a)(2).

While the Agency expects that adoption of the draft final rule might result in a general increase in the numbers of reports submitted, it is worth noting that much of that increase may well be the result of increased awareness and understanding on the part of pesticide registrants of their reporting responsibilities under the statutory requirement, rather than as a result of the rule. Much of the rule clarifies the existing reporting requirements. In addition, the draft final rule exempts more types of reports than current requirements and it simplifies the formatting and submission of less serious or more common types of incident reports.

This Information Collection Request (ICR) is an amendment of an existing ICR that is currently approved under OMB control #2070-0039 (EPA ICR #1204.03). The Environmental Protection Agency (EPA) is proposing to amend the existing ICR to reflect anticipated changes in the reporting and recordkeeping requirements. On

September 24, 1992 (57 FR 44290), EPA proposed several amendments to the existing policy which defines the reporting obligations of registrants under FIFRA §6(a)(2). A proposed ICR was also prepared and made available for comment at that time, and the comments that EPA received on both the proposed rule and the proposed ICR are included in the public docket for the proposed rule. These comments were considered during the development of a draft final rule and a draft ICR in 1996.

In response to concerns about the estimated burdens which were expressed by the regulated community based on the 1996 draft rule and ICR, EPA sought additional comments on the proposed amended ICR. Accordingly, a public comment period was provided, beginning August 12, 1996 and closing November 6, 1996. These additional comments were considered during the development of the draft final rule and are reflected in this draft ICR.

2. Need for and Use of the Collection

a) Need/Authority for the Collection

This information collection stems from a non-discretionary statutory requirement. Submission of information about unreasonable adverse effects is specifically required under section 6(a)(2) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) (7 USC 136d(a)(2)):

> "If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator."

b) Use/Users of the Data

The Office of Pesticide Programs is the primary user of the information that registrants would submit to the Agency under FIFRA section 6(a)(2). The information submitted is an essential component of the Agency's pesticide registration and reregistration programs because it requires the submission of important information regarding a pesticide's adverse effects -- information which may not have been available at the time of the Agency's initial review of a registration application. Because this information has possible significant consequences to human health or the environment, had the information been available earlier, the Agency's determination with regard to the registration of the pesticide may well have been different. If warranted by the information provided, EPA may need to amend the registration in order to address the concerns raised by the information.

In essence, this information provides an important means of focusing EPA attention on key problem areas regarding the use of the pesticide in question. The adverse effects information submitted under section 6(a)(2) is considered by EPA in

conjunction with information which supports continued use of the active ingredient, in order to determine whether pesticides containing the active ingredient should be reregistered, or whether the terms and conditions of registration should be changed. This type of information may also be pertinent to granting emergency exemptions under section 18 of FIFRA.

Registrants perform studies voluntarily in support of registration applications or in response to data call-ins issued by EPA. The authority to call in data is found in section 3(c)(2)(B) of FIFRA, and is covered by a different ICR approved by OMB. The outcome of those studies -- whether they demonstrate known effects or new adverse effects -- are carefully analyzed by registrants and presented to the Agency. This rule does not impose the requirement to perform studies but merely to identify and promptly submit adverse effects findings to the Agency.

Many registrants have indicated that adverse effects information is valuable to them as well. According to feedback that EPA has received, registrants acquire and use this information as a way of determining whether actual use circumstances reveal new risk issues that did not emerge when the data were developed for the original registration application. These registrants believe that it is an integral part of their product stewardship program and that collecting, analyzing and reacting to adverse effects information is essential to the way in which they conduct business as a routine matter. Registrants who actively seek 6(a)(2) information justified their actions under the following headings: product stewardship, customer relations, minimizing liability, and protecting or expanding market share.

3. The Respondents and the Information Requested

a) Respondents' Standard Industrial Classifications (SICs)

The collection applies to all pesticide registrants. The SICs assigned to the businesses required to submit a response under this collection activity are 286 and 287.

b) Information Requested

i) Data Items

As further defined by the final rule implementing the FIFRA section 6(a)(2) requirements, registrants are required to report on: 1) studies showing new or more severe toxicological responses than previously reported of any type in any strain of test organism; 2) epidemiological or exposure studies of human population groups; 3) studies or incidents tending to show lack of efficacy of certain pesticide products with public-health related uses; 4) incidents involving toxic or adverse effects to non-target organisms; 5) information on excess residues on food or feed, or residues in surface water, ground water or drinking water; 6) information on metabolites, degradates, contaminants or impurities which may be of toxicological concern; (7) information

showing that certain health-related products fail to perform as claimed or that pests have developed resistance to a product; and 8) other information which may be relevant to risk/benefit determinations of any type.

This ICR amendment no longer includes the estimate for burden hours associated with recordkeeping which is included in the existing ICR. When the final rule is promulgated, EPA will eliminate the existing recordkeeping requirement associated with the maintenance of information related to FIFRA section 6(a)(2) submissions. Registrants must still maintain records relating to the registration of the pesticide product, but the burdens associated with that recordkeeping are already covered by another ICR approved by OMB.

ii) Respondent Activities

Respondents must 1) read the final rule or instructions, 2) plan activities to ensure required information is identified and submitted, 3) process, compile and review information for accuracy and appropriateness, 4) complete written instruments to effectuate a submission, and 5) submit the information to EPA. In addition, as a part of the initial implementation for the final rule, the registrant must conduct a "screening" or "initial review" of their existing records. The purpose of this initial exercise is to identify specific information that is within the registrant's possession which hasn't already been submitted to EPA, but which meets the criteria under the final rule for submission under FIFRA section 6(a)(2).

Since section 6(a)(2) requires the submission of certain information when it is acquired by a registrant, any information meeting the criteria for submission under section 6(a)(2) which happens to be in the possession of the registrant upon the effective date of the final rule, and which has not already been submitted to EPA, would need to be submitted to EPA immediately. The Agency recognizes that this could impose a significant burden, and also that some of this information may be out-dated. Therefore the draft final rule limits the type of information that should be a part of this initial "screening" to only very serious incidents involving humans, domestic animals or wildlife. For these types of incidents, an inventory of the information is to be submitted. Up to a year is allowed for submitting such inventories.

Under FIFRA section 6(a)(2), as implemented by the final rule, pesticide registrants have absolutely no obligation to create or seek out this information. Such activities may be conducted by the registrant in support of pesticide registration under FIFRA section 3, or reregistration under section 4 (which are approved by OMB under separate ICR approvals), or in the normal course of business, such as following up on consumer complaints to gather more information. Regardless of how the information comes into the possession of the registrant, once the registrant acquires information subject to submission under section 6(a)(2), as defined by the final rule, the registrant must submit it to EPA.

4. <u>The Information Collected--Agency Activities, Collection Methodology, and</u>

Information Management

a) Agency Activities

The Agency will continue the following current activities with regard to the FIFRA section 6(a)(2) program: 1) answering questions and providing guidance to respondents; 2) receiving and reviewing data submissions; 3) recording the submissions; 4) analyzing claims of confidentiality and providing appropriate protection; and 5) storing the data submitted.

In addition, upon the issuance of the final rule, the Agency plans to meet with representatives of the regulated industry before the effective date of the regulation. Through these meetings, EPA intends to provide the registrants with an opportunity for further explanation with regard to the final rule, as well as to allow for continued discussions with regard to the specifics of submitting the required information to EPA. Since the final rule provides ample flexibility with regard to the vehicle, format and methods of submissions, EPA will be working with the respondents to identify the least burdensome means and most efficient ways to submit and manage the data. In fact, the Agency has set the final rule's effective date for nine months after publication in order to provide ample time for the Agency and respondents to prepare for implementation.

b) Collection Methodology and Management

This collection is not a survey, and there is no prescribed form or format for the required submission. The final rule allows flexibility in the method or format for the required submission. In essence, the final rule specifies the types of data that should be reported to the extent the information is available and the reporting timeframes. For incident information (but not studies), these vary according to the significance of the information.

Scientific studies containing 6(a)(2) information are assigned a Master Record Identifier Number as are all other pesticide studies. Adverse effects incident reports are entered into the Incident Data System, a computerized data base which can track incidents by chemical, submitter, type of incident, date of submission, and other parameters. All 6(a)(2) submissions are screened by a 6(a)(2) team representing all divisions within the Pesticide Program. Data are forwarded to and reviewed by pesticide product managers and science reviewers for relevance to the regulatory status of the pesticide product(s) to which the submitted information pertains. The public may access the data by contacting the Office of Pesticide Programs' 6(a)(2) Officer or the Agency's Freedom of Information Office.

c) Small Entity Flexibility

The U.S. pesticide industry includes two types of registrants: (1) those who buy the active ingredient(s) for their registered pesticide products, and (2) those who do not

buy the active pesticide ingredient(s) for their registered products. Often the second type of registrant produces the active ingredient from raw materials. Thus, EPA calls the second type of registrant a "basic producer". Basic producers are generally large enterprises employing over 100 employees with annual sales over $10 million per year. Basic producers are estimated to number about 250 and constitute approximately 10% of pesticide registrants. The other 90% of pesticide registrants are often small businesses. The requirements of FIFRA section 6(a)(2) related to studies fall largely on basic producers because they are the registrants most likely to generate and possess data subject to the information collection. Formulators (companies that do not manufacture active ingredients) are exempt from generating most health effects data required to support registration except for product-specific acute toxicity studies.

Both basic producers and formulators, however, may register and market end use products and receive incident reports from users of their products as well as other sources such as state regulatory agencies. The number of incident reports associated with a pesticide product depends on such variables as the volume of sales of that product, and whether it is sold to the general public or restricted to experienced and trained applicators. Thus, it is difficult to generalize about the relative burden of incident reporting in terms of small versus large companies. Numbers of registrations held is also a potential factor in reporting. Regardless of the size of the registrant, however, in this draft final rule EPA has provided greatly simplified reporting and extended timeframes, and in some cases, total exemptions for the most common types of incidents. These modifications should adequately address any potential small entity impacts.

d) Collection Schedule

The information required to be submitted under FIFRA section 6(a)(2) is not based on any schedule because the information is non-repetitive in nature. As such, the information required to be submitted by respondents is generally on an "as received basis". Like other 6(a)(2) policy statements before it, this rule establishes time limits within which reportable information received by registrants must be submitted to EPA. The final rule outlines reporting timeframes that vary according to the organism exposed and the relative severity or rarity of the alleged effects.

5. Non-duplication, Consultations, and Other Collection Criteria

a) Non-Duplication

The information required to be submitted is generally available only from registrants who have opted to secure registration of their pesticide product(s). The only feasible means of collecting the required information is from pesticide registrants because it is either health and safety data generated, owned or used by the registrants, or is submitted to registrants by consumers and other interested parties. The existing information collection avoids duplication by limiting the submission

requirements under FIFRA section 6(a)(2) to information which has not been submitted to the Agency previously. The information collection to be amended continues this limitation. Further, it exempts information submitted under section 8(e) of the Toxic Substances Control Act . Information in published articles is generally also exempt from submission**.**

b) Consultations

In September of 1992 a proposed rule on section 6(a)(2) reporting requirements was published in the *Federal Register*, along and its accompanying Information Collection Request (ICR). Both were made available for public comment. In addition, the Agency received several comments from the public as a part of EPA's regulatory reinvention initiative.

In August of 1996, EPA published and sought comments on a revised ICR reflecting the June 1996 draft final rule language. In addition, two meetings were held with interested parties to discuss their comments on both the draft final rule language and the burden estimates in the ICR.

This amended information collection request reflects the comments the Agency received and changes the Agency made in response to the public comments received. In this request for an ICR amendment, the Agency estimates, which are presented in section six of this document, are based on more recent data about the numbers and types of submissions EPA receives annually under the existing collection, and projections about potential reporting activities under the amended final rule.

c) Effect of Less Frequent Collection

Under FIFRA section 6(a)(2) the information collection activity is a one time, non-repetitive submission of information. As such, there is no set interval for multiple collections**.** The information is submitted one time, according to the timeframes described in the rule for various categories of information.

d) General Guidelines

This information collection is well within the guidelines provided under the Paperwork Reduction Act and the implementing regulations issued by OMB. It should be noted, however, that even though this collection does not contain any specific recordkeeping requirements, the EPA requirements in 40 CFR Part 169.2(k) state that records containing research data relating to registered pesticides be retained as long as the registration is valid and the producer remains in business. Registrations are valid until they are either voluntarily canceled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA guidelines specifying that data other than health, medical or tax records not be required to be retained for more than three years will be exceeded for those studies which are required to support

registration or reregistration under FIFRA section 3 or section 4, and which show adverse effects that make them reportable under section 6(a)(2). The burdens associated to this recordkeeping requirement have already been approved by OMB under another ICR and are therefore excluded from this ICR.

e) Confidentiality and Sensitive Questions

i) Confidentiality

Data submitted to the Agency are handled strictly in accordance with the provisions of the FIFRA Confidential Business Information (CBI) Security Manual which affords respondents the protections specified in FIFRA section 10. This manual contains instructions relative to all contact with confidential documents. The manual includes discussion of responsibilities of EPA employees, physical security measures, CBI typing, copying, transfer and destruction procedures, computer security, and internal division procedures. The manual provides that all CBI must be marked as such, must be kept in double locked areas, tracked by document control officers, and destroyed in a secured paper shredder. If the information is not protected under FIFRA section 10, and it is not protected from release under FOIA, EPA would be obligated to make it available to members of the public upon request.

ii) Sensitive Questions

No questions of a sensitive or private nature are included in this information collection. If information of a sensitive nature is submitted, the Agency will protect it appropriately, as provided by the Privacy Act or other relevant statutes.

6. <u>Estimating the Burden and Cost of the Collection</u>

a) Estimating Respondent Burden

To estimate the respondent burden under the new 6(a)(2) rule requirements, the Agency used statistics from the last fiscal year for which complete statistics are available (FY96), and also compared these to several preceding years. During this period, the number of studies and study related-submissions submitted under section 6(a)(2) showed a downward trend. This is probably due to the fact that EPA required many repeat and new studies from registrants in order to meet the reregistration requirements of the 1988 amendments to FIFRA. Many of those studies have now been submitted, so it is likely that the peak years for reregistration study submissions are past. In FY 1996, 400 study-related 6(a)(2) submissions were received, of which 100 were simply letters notifying EPA of possible adverse effects in incomplete studies. For purposes of this analysis, the Agency will assume that 400 study-related submissions is an appropriate number to expect annually. This gives some margin for

new registrations and studies concerning pest resistance, which is a new requirement of this rule, even as reregistration-related submissions continue to decline.

During FY 1996, EPA received 1,084 submissions from registrants containing about 7,770 incident reports. Of the total, 2,782 were individual incident reports, and the rest were included in summary reports, which the Agency encourages for more common types of incidents, and which this final rule will specifically require for certain categories of incidents. Incident submissions have shown an upward trend over the past five years. The increase is most likely attributable to increased awareness of 6(a)(2) obligations in the registrant community. For purposes of this analysis the agency believes that 7,770 is a reasonable baseline figure. In addition, based on EPA FY96 statistics, there are 2,100 registrants that have the potential of submitting 6(a)(2) information. For purposes of this analysis, we are assuming that all of these registrants will submit 6(a)(2) information each year.

The Agency expects that publishing the final rule will result in more submissions due to increased awareness among registrants and clearer definitions of what EPA wants. In addition, the rule adds some new requirements, such as information on pest resistance. On the other hand, the rule will also shift some incident reporting which may now be submitted as individual reports to a quarterly summary (which should greatly reduce the burden for the most common types of incidents), and provides several new exemptions that will reduce the burden.

The Agency has no reliable method of estimating the overall impact or net effect of changed requirements and simplified reporting methods. Historical data show that fewer than one hundred different registrants per year actually made submissions of either studies or incident reports. (These two groups are not necessarily the same companies). It is possible that since these registrants include some of the largest companies and many manufacturers of home-use and pet-care products (which generate large numbers of incident reports), the Agency may already be receiving a high proportion of what is reportable. It is also possible, however, that there are registrants who have not recognized or interpreted their obligations under section 6(a)(2) in the past in the manner this rule requires, and consequently will begin to make or substantially increase their submissions, particularly in the area of incident reporting.

The Food Quality Protection Act of 1996 (FQPA) adds another factor that could lead to increased submissions of studies. The FQPA requires the Agency to consider all routes of exposure to a pesticide chemical when making decisions relating to residues in foods (tolerances). As a consequence, the Agency has recently informed the registrant community (Pesticide Registration Notice 97-1) that they may wish to generate various kinds of information to support new tolerance applications or the reassessment of all existing tolerances which is required by the FQPA. A study showing exposure through food, feed or water greater than previously reported is reportable under 6(a)(2).

If publishing the rule has a low impact, the Agency estimates reporting of both studies and incidents might increase by 25 percent. If the final rule has a high impact, reporting levels could increase up to three-fold. For the purposes of this clearance, the Agency believes it would be prudent to allow for a 50 percent increase in the submission of studies, and a 100 percent increase in the number of incident reports. This would result in an estimated annual submission of 600 studies and 15,540 incident reports, with an estimated annual total registrant reporting burden of 3,540 hours for studies (5.90 hours per response) and 35,742 hours for incidents (2.3 hours per response). See Tables 1 and 2.

For purposes of determining the number of employees that will potentially need to be trained, EPA assumed that an average of 15 employees per registrant or 31,500 individuals will need to be trained in the first year of implementing the new rule, with an average of 10 employees per registrant or 21,000 individuals requiring training each year thereafter. Please note that this estimate is strictly an average. The actual number would range from one person in a small company to several dozen in a large company. The Agency does not believe that a high proportion of people in any company need detailed training in 6(a)(2) requirements. Most employees who are likely to receive information concerning the effects of pesticide products simply need to be aware of the need to pass information concerning their company's products along to an appropriate individual or staff.

The **total first year burden hours and cost** associated with the rule includes the estimated total for submissions related to studies (3,540 hours and $257,760) (Table 1), for submissions related to incidents (35,752 hours and $2,778,552) (Table 2), and the total estimated burden hours related to becoming familiar with the changes to the requirements, the one-time review for certain unreported incident information and the potential occasional need to track a submission for follow-up (156,660 hours and $12,631,920) (Table 6). The total first year burden is estimated to be **195,942 burden hours** and the total first year cost is estimated to be **$15,668,232**, or **an average of 93.31 hours and $7,461 per registrant**. (Table 8)

The total burden for registrants during **subsequent years** is estimated to be **83,172 hours** and the total cost is estimated to be **$8,127,132**, or **an average of 39.61 hours and $3,870 per registrant**. This includes the total estimated burden hours for submissions related to studies (3,540 hours and $257,760) (Table 1), for submissions related to incidents (35,752 hours and $2,778,552) (Table 2), and the total estimated burden hours related to continued training and the potential occasional need to track a submission for follow-up (43,890 hours and $5,090,820) (Table 7). (Table 9)

Estimates were provided at the first year and subsequent years. The registrants will incur the greatest burden in the first year of implementation, but experience significant reductions in hours expended in subsequent years. Part of the first year burden is associated with the requirement to review incident files and submit an inventory of certain very serious incidents if they had not been submitted before and occurred within the time frame specified in the final rule, as well as an increase in

training effort.

The following tables illustrate the estimated respondent burden and costs:

Table 1: Annual Respondent Burden/Cost Estimates per Submission - STUDIES					
	BURDEN HOURS (PER YEAR)			TOTAL	
COLLECTION ACTIVITIES	Mgmt $128/hr	Tech $87/hr	Cler $39/hr	Hours	Costs ($)
Read Instructions	0.2	1.0	0.00	1.20	112.60
Create Information	0.00	1.0	0.00	1.00	87.00
Compile and Review	0.1	1.0	0.00	1.10	99.80
Complete Paperwork	0.00	0.1	1.0	1.10	47.70
Store and Maintain Data	0.00	0.5	1.0	1.50	82.50
TOTAL	0.30	3.60	2.00	5.90	429.60

ANNUAL BURDEN: 5.90 Total Hours x 600 Studies = 3,450 Hours

ANNUAL COSTS
(a) Management: 0.30 hours x $128 x 600 Studies = $ 23,040
(b) Technical: 3.60 hours x $87 x 600 Studies = $187,920
(c) Clerical: 2.00 hours x $39 x 600 Studies = $ 46,800
TOTAL = $257,760

Table 2: Annual Respondent Burden/cost Estimates per Submission - INCIDENTS					
	BURDEN HOURS (PER YEAR)			TOTAL	
COLLECTION ACTIVITIES	Mgmt $128/hr	Tech $87/hr	Cler $39/hr	Hours	Costs ($)
Read Instructions	0.2	0.5	0.00	0.70	69.10
Create Information	0.00	0.5	0.00	0.50	43.50
Compile and Review	0.1	0.2	0.00	0.30	30.20
Complete Paperwork	0.00	0.00	0.5	0.50	19.50
Store and Maintain Data	0.00	0.1	0.2	0.30	16.50
TOTAL	0.30	1.30	0.70	2.30	178.80

ANNUAL BURDEN: 2.30 Total Hours x 15,540 Incidents = 35,742 Hours
ANNUAL COSTS
(a) Management: 0.30 hours x $128 x 15,540 Incidents = $ 596,736
(b) Technical: 1.30 hours x $87 x 15,540 Incidents = $1,757,574
(c) Clerical: 0.70 hours x $39 x 15,540 Incidents = $ 424,242
TOTAL = $2,778,552

Table 3: Total Annual Burden/Costs for Required Submissions			
	Per Submission Estimates	Total Submissions Expected each Year	Totals

	Burden Hours	Costs ($)		Burden Hours	Costs ($)
Studies	5.9	429.60	600	3,540	257,760
Incident	2.3	178.80	15,540	35,742	2,778,552
TOTAL	8.2	608.40	16,140	39,282	3,036,312

Table 4: Registrant Burden/Cost Estimates for Additional Activities - First Year

Activities/registrants		Burden Hour per Respondent			Totals	
		Mgmt $128/hr	Tech $87/hr	Cler $39/hr	Hours	Costs ($)
Training	Who needs instructions	0.5	0.00	0.00	0.5	64.00
	Learn new instructions	0.8	2.5	1.0	4.3	358.90
One-time Review	Review existing files	0.20	1.0	4.0	5.2	268.60
	Compile & Review Submission	0.20	1.5	0.8	2.5	187.30
	Complete Submission	0.1	0.5	1.0	1.6	95.30
Follow-up Tracking		0.00	0.10	0.2	0.3	16.50
Total		1.8	5.6	7.0	14.4	990.60

Table 5: Registrant Burden/Cost Estimates for Additional Activities - Subsequent Years

Activities/registrants		Burden Hour per Respondent			Totals	
		Mgmt $128/hr	Tech $87/hr	Cler $39/hr	Hours	Costs ($)
Training	Who needs instructions	0.5	0.10	0.00	0.6	72.70
	Learn new instructions	0.50	1.5	1.0	3.0	233.50
Follow-up Tracking		0.00	0.10	0.2	0.3	16.50
Total		1.0	1.7	1.2	3.9	322.70

Table 6: Total Registrant Burden/Cost Estimates for Additional Activities - First Year

Activity		Per Registrant - Total		# Expected	Totals	
		Hours	Costs ($)		Hours	Costs ($)
Training	Who needs instructions	0.5	64.00	2,100	1050	134,400
	Learn new instructions	4.3	358.90	31,500	36,750	11,305,350
One-time Review	Review existing files	5.2	268.60	2,100	10,920	564,060
	Compile & Review Submission	2.5	187.30	2,100	5,250	393,330

	Complete Submission	1.6	95.30	2,100	3,360	200,130
Follow-up Tracking		0.3	16.50	2,100	630	34,650
Total		14.4	990.60		156,660	12,631,920

Table 7: Total Registrant Burden/Cost Estimates for Additional Activities - Subsequent Years

Activity		Per Registrant - Total		# Expected	Totals	
		Hours	Costs ($)		Hours	Costs ($)
Training	Who needs instructions	0.6	72.70	2,100	1260	152,670
	Learn new instructions	3.0	233.50	21,000	42,000	4,903,500
Follow-up Tracking		0.3	16.50	2,100	630	34,650
Sub-Total		3.9	322.70		43,890	5,090,820

Table 8: Total Estimated Burden/Costs for Registrants - First Year					
	Per Activity Total Estimates		Total Activities Expected First Year	Totals	
	Burden Hours	Costs ($)		Burden Hours	Costs ($)
Studies	5.9	429.60	600	3,540	257,760
Incident	2.3	178.80	15,540	35,742	2,778,552
Training	0.5	64.00	2,100	1,050	134,400
	4.3	358.90	31,500	135,450	11,305,350
Review	9.3	551.20	2,100	19,530	1,157,520
Follow-up	0.3	16.50	2,100	630	34,650
TOTAL	22.6	1,599.00	53,940	195,942	15,668,232

Table 9: Total Annual Burden/Costs for Registrants - Subsequent Years					
	Per Activity Total Estimates		Total Activities Expected First Year	Totals	
	Burden Hours	Costs ($)		Burden Hours	Costs ($)
Studies	5.9	429.60	600	3,540	257,760
Incident	2.3	178.80	15,540	35,742	2,778,552
Training	0.6	72.70	2,100	1,260	152,670
	3.0	233.50	21,000	42,000	4,903,500
Follow-up	0.3	16.50	2,100	630	34,650
TOTAL	12.1	931.10	41,340	83,172	8,127,132

c) Annual Agency Burden/Cost Estimates

We based our estimates of the burden and costs to the Agency on prior experience in processing the submissions now received by the Agency. Because Agency costs have risen since this collection was last cleared and we estimate increased submissions by registrants due to greater availability of data, we have revised our estimates accordingly. The screening and managing of submitted information involves fairly high level technical personnel at all stages, including data entry. For purposes of this estimate we have used an average grade of GS-14, Step 5. Although some tasks can be performed by clerical workers (GS-7, Step 5), in practice relatively few are, due to the complex and variable nature of submitted material. The total Agency burden hours estimated for this information collection activity is 5,147 hours (0.63 hours per response for studies and incidents (Table 10)). The Agency also expects to incur some first year costs due to the need to educate both the

registrant community and EPA staff about the rule, and to plan for compliance activities. This could use up to one-half a Full Time Equivalent for management personnel at a cost of about $33,500.

Table 10: ANNUAL AGENCY BURDEN/COST ESTIMATES				
	BURDEN HOURS (per year)		TOTAL	
COLLECTION ACTIVITIES	Mgmt/Tech $74/hr (GS-14, Step 5)	Cler $28/hr (GS 7, Step 5)	Hours	Costs ($)
Screen submitted information	0.13	0.00	0.13	$9.62
Record, file and track submissions	0.40	0.10	0.50	$32.40
TOTAL	0.53	0.10	0.63	$42.02

ANNUAL BURDEN: 0.63 Total Hours x 16,140 submissions = 10,168 Hours

ANNUAL COSTS
(a) Management: 0.53 hours x $74 x 16,140 submissions = $633,011
(b) Clerical: 0.10 hours x $28 x 16,140 submissions = $ 45,192
TOTAL = $678,203

d) Bottom Line Hours and Costs/ Master Table

The total estimated burden and costs associated with the final rule are presented in Table 11 below.

Table 11: MASTER TABLE	TOTAL	
	Hours	Cost
Annual Respondent Burden/Cost Estimates (Year 1):	195,942	$15,668,232
Annual Respondent Burden/Cost Estimates (Years 2 & 3):	83,172	$8,127,132
Annual Agency Burden/Cost Estimates:	10,168	$678,203

For the purposes of determining the annual amount of burden hours needing OMB approval, the Agency has decided to spread the first year burden over the three year approval period by taking the difference between the first year burden and subsequent years burden and dividing it by 3 and then adding that figure to the estimated total annual burden for subsequent years. EPA has therefore requested that OMB approve for three years an **annual burden of 120,762 hours** ((112,770÷3) +83,172), with a **total estimated costs of $10,640,832** ((7,541,100÷3)+ 8,127,132). Total annual responses were also calulated the same way, resulting in an estimated total potential response of 45,540 ((53,940 - 41,340) ÷3 + 41,340). Although unlikely to reflect actual per respondent burden, given the variance in the need to submit studies, incident reports, and train employees, the **average burden is estimated to be 57.5**

hours per registrant (120,762 total hours ÷ 2,100 registrants), with an estimated **average cost of $5,067 per registrant** (10,640,832 total cost ÷ 2,100 registrants). Upon renewal of this ICR in 3 years, the burden associated with the first year of the rule will be eliminated.

e) Reason for Change in Burden

It is clear that not all registrants currently submit the required 6(a)(2) information, and, since the burden hour estimates were based on the Agency's experience with submissions in the past, the previous burden hour estimate reflects this. However, as discussed under section 6 of this ICR, the Agency has increased the burden estimates significantly because it is likely that the publication of the final rule will alert registrants who may not currently understand their obligations under section 6(a)(2) to begin reporting. The rule also adds requirements to report pest resistance for categories of products not previously subject to this requirement, which is expected to generate several hundred submissions that may be either scientific studies or incident reports. The total increase in burden is therefore related to both a program change and an adjustment. The amount attribiutable to each is not really determinable, so the Agency distributed the total increase equally between the two categories (110,382 ÷2 = 55,191).

In addition, the Agency does not believe that this estimate is reflective of an individual registrants costs or burdens, since the individual costs and burdens are directly related to such things as the number of products, the number of employees, and the number of incident reports or studies the individual registrant receives and therefore must provide to EPA. The estimate, however, assumes that each registrant would participate in the activities described and that the participation would be at the same level for each registrant. Although this estimate is not reflective of an individual registrants costs or burdens, the total estimated burden and costs more than adequately covers the variation in the level of participation among the registrants.

The primary reason the costs change was due to the wage rates used for both the registrants and the Agency. The last 6(a)(2) ICR used wage rates that only included benefits. The wage rates used in this analysis are loaded, which means that they include other external costs such as rent, machinery, land, etc., as well as benefits. A loading factor of 2.1 is typically used when estimating this rate.

Since this estimate is based on several predictions and assumptions, the Agency will reevaluate these estimates in three years, when the Agency seeks an extension of the Information Collection Request. At that time, the Agency hopes to have some indication of the reporting trends under the new provisions, and anticipates some reductions associated with the availability of electronic submissions, which the Agency expects to implement as soon as issues associated with protecting CBI and ensuring data integrity are resolved.

(f) Burden Statement

The reporting burden for the first year of this collection of information includes an estimated 5.9 hours per submission of scientific studies, 2.3 hours per submission of incident reports, 9.3 hours per registrant for reviewing their records for, and submitting to the Agency, any fatality and hospitalizations not previously submitted to the Agency, 0.3 hours per registrant for the potential need to track a submission in order to provide subsequent follow-up, and 4.8 hours per registrant for rule familiarization and training. The annual reporting burden for this collection of information in subsequent years is estimated to be 5.9 hours per submission of scientific studies, 2.3 hours per submission of incident reports, 0.3 hours per registrant for the potential need to track a submission in order to provide subsequent follow-up, and 3.6 hours per registrant for continued training. Although the actual reporting needs of registrants vary greatly, based on the total annual burden hours approved by OMB, the average burden per registrant would be 57.5 hours, with an average cost of $5,067.

Burden means the total time, effort, or financial resources expended by persons to provide the necessary information to the EPA. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing information, and providing information; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for the related regulation is displayed at 40 CFR 9.1.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to: Director, Information Management Division, OPPE, Mailcode 2137, Environmental Protection Agency, 401 M St., S.W., Washington D.C. 20460, or by e-mail to: farmer.sandy@epamail.epa.gov. Be sure to include the appropriate OMB approval or EPA ICR number in any correspondence. Forms and other submissions discussed in this ICR should be sent to EPA at the address listed in the regulation and should not be sent to this address.